

Translation

PATENT COOPERATION TREATY

PCT/EP2003/014762



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P62096	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/014762	International filing date (day/month/year) 19 December 2003 (19.12.2003)	Priority date (day/month/year) 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC C07K 14/47		
Applicant	ERNST-MORITZ-ARNDT-UNIVERSITÄT GREIFSWALD	

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.
<input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>67</u> sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 20 July 2004 (20.07.2004)	Date of completion of this report 04 April 2005 (04.04.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/014762

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

the international application as originally filed  
 the description:

pages 1-63, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages 64-65, filed with the letter of 18 March 2005 (18.03.2005)

the claims:

pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19)  
 pages \_\_\_\_\_, filed with the demand  
 pages 1,2,4, and 3 (letter 18.03.2005), filed with the letter of 10 March 2005 (10.03.2005)

the drawings:

pages 1-13, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the sequence listing part of the description:

pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages 1-61, filed with the letter of 19 August 2004 (19.08.2004)

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
 the language of publication of the international application (under Rule 48.3(b)).  
 the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority in written form.  
 furnished subsequently to this Authority in computer readable form.  
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, Nos. 26-28  
 the drawings, sheets/fig \_\_\_\_\_

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/14762

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-19, 23-25	YES
	Claims	20-22	NO
Inventive step (IS)	Claims	1-19, 23-25	YES
	Claims	20-22	NO
Industrial applicability (IA)	Claims	1-25	YES
	Claims		NO

## 2. Citations and explanations

1. The present application states on page 1 of the description that it relates to a mutated nucleic acid sequence which codes for a variant of human YY1. However, the variant of YY1 disclosed in the present application is a variant of YY1 from the rat (SEQ ID NO. 3 and 4). A variant of human YY1 is neither disclosed nor claimed.
2. Claim 11 relates to a method for determining the tendency to contract type 1 diabetes on the basis of mutations of human YY1 (SEQ ID NO. 6). However, it is not clear from the description which mutations of YY1 are responsible for said tendency; it is merely stated that sequence variations of YY1 are expected (see page 30, third paragraph). In addition, the description indicates that the expression profile of a type 1 diabetic is individual (see page 30, fourth paragraph to page 31, first paragraph). A person skilled in the art would not be able to carry out said method on the basis of this information, because he would not know to which mutations he would have to refer in order to obtain clear evidence of a tendency to contract type 1 diabetes (PCT Article 5).
3. Claim 20 relates to a transgenic animal which contains DNA that codes for a protein with the sequence SEQ ID NO. 2. It is not clear from the data

currently available in the description to what extent an animal of this kind differs from the known BB/OK rat, which contains this sequence naturally. If the claimed transgenic animal were to have the same DNA as the BB/OK rat, that is, if, for example, no vector DNA of any kind were additionally present in the transgenic animal to enable a distinction to be drawn between these two animals, the transgenic animal would not be considered novel (PCT Article 33(2)).

5. In relation to the cited prior art and in the light of the foregoing observations, the present invention may be said to meet the PCT requirements for novelty and inventive step (PCT Article 33(1) to (3)).